510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K010256**

Applicant information:

Date Prepared:	March 1, 2001
Name:	**Opti-Centre Laboratories Inc.**
Address	4375 Ouimet Street Sherbrooke (Quebec) Canada JIL 1X5
Contact Person:	Robert Mercure
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USA Consultant:	Martin Dalsing Medvice Consulting, Inc.
Phone number	(970) 243-5490 Fax (970) 243-5501 Email: mdalsing@gj.net

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**UltraVue/P 2000T (hioxifilcon B) & UltraVue/C 2000T (hioxifilcon B) Soft (Multifocal Toric) Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)**

Purpose of 510(k) submission:

NEW DEVICE ~

Opti-Centre Laboratories proposes to market and sell in the United States interstate commerce, a lathe-cut soft contact lens of the (hioxifilcon B) soft contact lens material and made available in a multifocal toric product configuration. Data supporting substantial equivalency to the predicate devices, performance and safety and efficacy of the (hioxifilcon B) polymer is contained in this submission.

Equivalent Devices:

The **UltraVue/P 2000T (hioxifilcon B) & UltraVue/C 2000T (hioxifilcon B) Soft (Multifocal Toric) Daily Wear Contact Lens** is substantially equivalent to the following predicate devices in terms of intended use and design. Predicate devices include:

- UltraVue/P and UltraVue/C multifocal manufactured by Opti-Centre Laboratories (K974599)
- OCU-FLEX 53 Toric Multifocal manufactured by Ocu-Ease Optical
- BENZ-G 3X manufactured by BENZ Research and Development Corp. (K964528)

Device Description:

The **UltraVue/P 2000T (hioxifilcon B) & UltraVue/C 2000T (hioxifilcon B) Soft (Multifocal Toric) Daily Wear Contact Lens** is fabricated from hioxifilcon B, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The front surface of the **UltraVue/P 2000T & UltraVue/C 2000T** soft contact lens is aspherical, with the anterior surface having a toric generated surface for the purpose of correcting vision in an eye that is astigmatic. The **UltraVue/P 2000T & UltraVue/C 2000T** are designed with two multifocal zones, as well as the edge shape being optimized to provide comfort without sacrificing tensile strength.

The **UltraVue 2000T** soft multifocal toric contact lenses are available in two versions. The **UltraVue/P 2000T** with a spherical central zone for the correction of distance vision and an aspherical annular zone for the correction of intermediate and near vision. The **UltraVue/C 2000T** with a spherical central zone for the correction of near vision and an aspherical annular zone for the correction of intermediate and distance vision. The lenses are available in clear and with a blue visibility handling tint, phthalocyanato (2) – (copper).

The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped; however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The non-ionic lens material, (hioxifilcon B) is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3 dihydroxypropyl methacrylate (Glycerol Methacrylate, GMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 51% hioxifilcon B and 49% water by weight when immersed in normal saline solution buffered with sodium bicarbonate.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 49% water by weight. The physical properties of the lens are:

Refractive Index	1.425
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	49 %
Specific Gravity	1.308 (dry) 1.136 (hydrated)
Oxygen Permeability	15×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

Intended Use:

The **UltraVue/P 2000T (hioxifilcon B) & UltraVue/C 2000T (hioxifilcon B) Soft (Multifocal Toric) Daily Wear Contact Lenses** are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia, possess astigmatism of 3.00 diopters or less and are presbyopic.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a quality assurance program already in place. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently marketed and distributed by Opti-Centre Laboratories, Inc. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the BENZ-G 3X, 510(k) #K964528. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2001

Opti-Centre Laboratories, Inc.
C/O Mr. Martin Dalsing
Official Correspondent and US Consultant
Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K010256
Trade Name: UltraVue/P 2000T (hioxifilcon B) and UltraVue/C 2000T (hioxifilcon B) Soft (Multifocal Toric) Daily Wear Contact Lenses (Clear & Blue Visibility Tinted, Lathe Cut)
Regulatory Class: II
Product Code: 86 LPL
Dated: January 18, 2001
Received: January 29, 2001

Dear Mr. Dalsing:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: **UltraVue/P 2000T (hioxifilcon B) & UltraVue/C 2000T (hioxifilcon B) Soft (Multifocal Toric) Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)**

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(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Myra Smith

(Division Sign-Off)
Division of Ophtnalmic Devices
510(k) Number K010256

Prescription Use X
(Per 21 CFR 801.109)

or

Over-The-Counter Use ___

(Optional Format 1-2-96)